

Remarks

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments. Applicants respectfully submit that the amendments are fairly based on the specification and respectfully request their entry.

35 U.S.C. § 101 REJECTION OF CLAIMS 1, 3-12, 32, 33, 39, 48 & 49

Claims 1, 3-12, 32, 33, 39, 48 and 49 are rejected under 35 USC § 101 for, in the Examiner's view, lacking utility. More specifically, the Examiner asserts that the claimed invention is not supported by a specific or substantial utility. Applicants respectfully traverse this rejection for the reasons set forth below.

Applicants first note that the utility requirement of § 101 is met either if the claimed subject matter has a "well-established" utility, or if a substantial, specific, and credible utility is disclosed in the specification.

An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (*e.g.*, properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.

Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001). For example, “some uses can be immediately inferred from a recital of certain properties.” *In re Folkers*, 344 F.2d 970, 974 (C.C.P.A. 1965) (explicitly undisturbed by *Brenner v. Manson*, 383 U.S. 519, 535 n.23 (1966), and *In re Kirk*, 376 F.2d 936, 949 (C.C.P.A. 1967) (Rich, J., dissenting)). In particular, when “newly discovered compounds [that] belong to a class of compounds, the members of which have become well recognized as useful for a particular purpose because of a particular property, the only reasonable conclusion is that the new compounds, also possessing that property, are similarly useful.” *Folkers* at 975, *see also* MPEP 2107.02.

In the instant application, the claimed subject matter comprises nucleic acid sequences encoding a human LCP protein. The claimed LCP gene sequences encode trans-membrane polypeptides, with an N-terminal signal peptide (page 7, ll. 5 – 8). These polypeptides also contain an LCCL domain, mutations within which have been shown to cause the deafness disorder DFN9 in humans (page 6, ll. 19 – 23). Also included in the polypeptides encoded by the gene sequence of the instant application is a discoidin domain, with a predicted amphipathic, membrane binding alpha helical structure at the C-terminal (page 6, line 24 through page 7, line 4). The polypeptides encoded by the claimed gene sequences also contain a truncated CUB domain, an extracellular domain found in mostly developmentally regulated proteins (page 6, ll. 12 – 18). These features of the encoded polypeptides were also independently identified by Kobuke et al. (*J. Biol.*

Chem., 276:34105-34114, 2001; enclosed in the IDS submission). Kobuke et al. also provided data demonstrating that the gene is up-regulated after vascular injury.

Applicants also wish to draw Examiner's attention to post filing date literature by Koshikawa et al. (*Oncogene*, 21:2822-2828, 2002; copy enclosed and listed on enclosed one page Form PTO-1449). Koshikawa et al. presented evidence that expression of the gene of the current application is significantly up-regulated in a significant fraction of lung cancers *in vivo* with high frequency in metastatic lesions. These findings are in agreement with Applicant's belief that the gene and encoded polypeptides are useful in developing therapeutics as well as diagnostics for neurological and developmental disorders and tumors (page 5 line 30 through page 6, line 2; page 7, ll. 2 – 4).

Because the claimed nucleic acid sequences of the instant application can be used to produce useful proteins or polypeptides, Applicants respectfully submit that the claimed invention is useful. According to the Federal Circuit, “[t]he threshold of utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (emphasis added). Therefore, Applicants respectfully request that the above rejection be withdrawn.

35 U.S.C. § 112, FIRST PARAGRAPH REJECTION OF
CLAIMS 1, 3-12, 32, 33, 39, 48 & 49

Claims 1, 3-12, 32, 33, 39, 48 and 49 are rejected under 35 USC § 112, first paragraph as non-enabled. Specifically, the Examiner appears to object to the “nucleic acid encoding a polypeptide comprising 90%, 95%, or 99% identity with SEQ ID NO: 2 or SEQ ID NO: 1113,” which the Examiner appears to identify as resulting in the impermissible broadening the scope of the claims beyond the ability of the skilled artisan to make and use, due to the enormous number of possible amino acid modifications. Applicants respectfully traverse this rejection for the reasons set forth below.

In response to the above rejection, Applicants have amended claims 1, 48 and 49 to delete the claim of sequences with a certain percent identity to either SEQ ID NO: 2 or SEQ ID NO: 1113, or SEQ ID NO: 3 or SEQ ID NO: 1114. As a result, the claims of sequences with a certain percent identity are now limited to only SEQ ID NO: 1115 or SEQ ID NO: 1116. SEQ ID NO: 1115 contains the novel splice junction sequence of LCP2, while SEQ ID NO: 1116 is the encoded polypeptide sequence of SEQ ID NO: 1115. Both are relatively short sequences that are part of SEQ ID NO: 1113 and SEQ ID NO: 1114, respectively. Thus, the descriptions that the Examiner identified as resulting in the impermissible broadening the scope of the claims, due to the extremely large number of polynucleotides broadly encompassed by the claims, has now been eliminated from claims 1, 48 and 49. Therefore, Applicants respectfully submit that the basis for the

above rejection, as it relates to claims 1, 48 and 49 and the claims directly dependent therefrom, has been eliminated.

Claims 1, 3-12, 32, 33, 39, 48 and 49 are further rejected under 35 USC § 112, first paragraph. Specifically, the Examiner objects to what he views as a lack of description sufficient to convey to one skilled in the art that the inventors had possession of the invention, at the time of filing. Applicants respectfully traverse this rejection for the reasons set forth below.

In response to the above rejection, Applicants point out that claims 1, 48 and 49 have been amended above to more clearly set forth the claimed invention. Applicants have amended claims 1, 48 and 49 above to delete the claim of sequences with a certain percent identity to either SEQ ID NO: 2 or SEQ ID NO: 1113, or SEQ ID NO: 3 or SEQ ID NO: 1114. As a result, the claims of sequences with a certain percent identity are now limited to only SEQ ID NO: 1115 or SEQ ID NO: 1116. SEQ ID NO: 1115 contains the novel splice junction sequence of LCP2, while SEQ ID NO: 1116 is the encoded polypeptide sequence of SEQ ID NO: 1115. Both are relatively short sequences that are part of SEQ ID NO: 1113 and SEQ ID NO: 1114, respectively. Applicants respectfully submit that in view of the above amendments to claims 1, 48 and 49, as supported by the original claims and specification, one of ordinary skill in the art can clearly determine

that Applicants were in possession of the invention at the time of filing. Thus, it is respectfully requested that the above rejections be reconsidered and withdrawn.

Early and favorable action is earnestly solicited.

Respectfully submitted,

AMERSHAM BIOSCIENCES CORP

By:



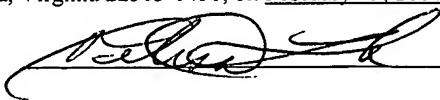
Yonggang Ji
Registration No.: 53,073
Agent for Applicants

Amersham Biosciences Corp
800 Centennial Avenue
P. O. Box 1327
Piscataway, New Jersey 08855-1327

Tel: (732) 980-2875
Fax: (732) 457-8463

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Signature:



Name:

Melissa Leck